REMARKS

In this Response, claims 1, 11, and 22 have been amended. No new claims have been added and no claims have been canceled. Amendment and cancellation of a claim is not to be construed as a dedication to the public of any subject matter. No new matter has been added.

Attached hereto is a marked-up version of the changes made to the claims by the current Amendment. The attached page is entitled "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**".

Rejections under 35 U.S.C. §102(b)

Claims 22 and 25

Claims 22 and 25 stand rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,800,478 to Chen *et al.* (Chen '478). In support of this rejection, the Office Action states that, "Chen et al discloses a flexible probe that is generally linear with light emitting diodes along the axis (Fig. 1.). Since the LED's are the only light emitting devices on the probe, they inherently emit substantially all the light from the probe (device)."

Claim 22, from which claim 25 depends, has been amended. As amended, claim 22 now recites a light delivery device comprising a generally linear member having a "transparent linear light emitting region" that is "surrounded by a substantially opaque region on each of its surfaces but its light emitting surface."

Chen '478 fails to teach or disclose the device recited in claim 22. First, Chen '478 fails to disclose a "transparent linear light emitting region" that is "surrounded by a substantially opaque region on each of its surfaces but its light emitting surface." Instead, Chen '478 teaches a substrate having light emitting sources mounted thereon (*see* **102** and **104** in FIGS. 1 and 2). The substrate and light emitting sources are "enclosed in a clear (light transparent) biocompatible polymer envelope **106,**" making the entire distal region of the device of Chen substantially transparent, *see* col. 8, lines 60-63. In this way, light can be dispersed in all directions, through either side of Chen's device. This is in direct contradistinction with the recitation in claim 22 of

a light emitting surface that is "surrounded by a substantially opaque region on each of its surfaces but its light emitting surface." As Applicant's specification teaches, the opaque region helps assure that only the tissue intended to receive light, receives such light (*see, e.g.,* pg. 20, lines 20-22, and pg. 21, lines 13-14 and 20-21).

In addition, Chen '478 fails to disclose emitting light to "produce a lesion in a pattern corresponding to the light emitting region." The device of Chen '478 is designed to spread light as wide as possible, it does not produce a lesion in a pattern corresponding to the light emitting region.

Applicant respectfully submits that, in view of the above Amendments and Remarks, the rejection of claims 22 and 25 under 35 U.S.C. §102(b) are improper and should be withdrawn. Because Chen '478 fails to teach or suggest why the device of claim 22 and 25 may be desirable, any rejection under 35 U.S.C. §103 would be similarly improper.

Rejections under 35 U.S.C. §103(a)

Claims 1-4 and 11-14

Claims 1-4 and 11-14 stand rejected under 35 U.S.C. §103(a) over U.S. Patent No. 6,143,019 to Motamedi *et al.* (Motamedi) in view of Chen '478. In support of the rejection the Office Action states:

> "Motamedi et al discloses a device and method for treating cardiac tissue using photodynamic therapy (Col. 6, lines 3-4). The fiber optic tip is applied to the heart through the endocardium (Col. 3, line 4). It is inherent that the light activated substances must be introduced into the tissue in some manner. Whether the photosensitizer is introduced locally or systemically would have been obvious to the skilled artisan. Motamedi et al does not disclose a specific pattern for the treatment probe. Chen et al teaches a flexible probe for light therapy with LED's mounted thereon. The probe may be linear or configured to a specific pattern (Col. 17, lines 49-50) due to the flexible substrate and manner of mounting the LED's. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the flexible light probe as taught by Chen et al in the invention of Motamedi et al to activate the photosensitizer to effect an interruption of the electrical "circuit" that causes cardiac arrhythmias."

Applicant disagrees with this rejection. In order to set forth a *prima facie* case of obviousness, the references must teach or suggest all the claim limitations; there must be some suggestion or motivation to modify the references or combine their teachings; and there must be a reasonable expectation of success, *see* MPEP §2143. The Office Action fails to set forth even a *prima facie* case of obviousness.

For one, the references fail to teach or suggest all the claim elements. Claim 1, from which claims 2-4 depend, has been amended and now recites a method for producing patterned lesions by subjecting cardiac tissue containing a photodynamic drug to a "light source arranged so as to produce a lesion in a pattern corresponding to the light source." Similarly, claim 11, from which claims 12-14 depend, has been amended and now recites a "light source arranged so as to produce a lesion in a pattern corresponding to the light source."

Neither Motamedi nor Chen '478 teach methods for producing lesions having patterns corresponding to the light source. A device having lights arranged in a certain pattern or fashion, does not read upon a device that forms lesions in a pattern corresponding to the light pattern, unless those lesion patterns are explicitly set forth. As described above, the device of Chen '478 is designed to spread light as wide as possible, it does not produce a lesion in a pattern corresponding to a light emitting region.

For the reasons set forth below, Lesh can not fill the deficiencies of these references. Therefore, Applicant submits that the rejections under 35 U.S.C. §103(a) are improper. Withdrawal of these rejections is respectfully requested.

Claims 5-10 and 16-21

Claims 5-10 and 16-21 stand rejected under 35 U.S.C. §103(a) over Motamedi in view of Chen '478 and U.S. Patent No. 6,164,238 to Lesh (Lesh). In support of the rejection the Examiner states:

> "Neither Motamedi et al nor Chen teach specific ablation patterns for specific cardiac conditions or methods. Lesh teaches methods to electrically

isolate specific areas of the heart using ablative means to treat arrhythmia. Lesh teaches that focal arrhythmia often originate from a tissue region along the pulmonary veins of the left atrium, and even more particularly in the superior pulmonary veins. The method of treating involves forming a circumferential conduction block, using an internal catheter with ablation means, which is located either (a) along a circumferential path of tissue in a pulmonary vein wall which circumscribes the pulmonary vein lumen and transects the electrical conductivity of the pulmonary vein relative to its longitudinal axis, or (b) along a circumferential path of tissue in a left posterior atrial wall which surrounds a pulmonary vein ostium and electrically isolates the pulmonary vein and the ostium from a substantial portion of the left posterior atrial wall including the other of the vein ostia. Lesh further teaches an external procedure wherein a circumferential conduction block of one or more pulmonary veins may be performed in an epicardial ablation procedure, wherein an ablation element is either placed around the target pulmonary vein or is translated circumferentially around it while being energized to ablate the adjacent tissue in an "outside-in" approach. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the photodynamic techniques of Motamedi et al as an equivalent alternative to traditional ablative methods to treat cardiac arrhythmias in the patterns and areas as taught by Lesh."

Applicant disagrees with this rejection, and again submits that the Office Action fails to set forth a prima facie case. For one, there is no motivation to combine the references. Motamedi teaches devices and methods for delivering energy to tissue to achieve a desired biological response. More specifically, Motamedi teaches the induction of local hyperthermia in cardiac tissue in order to trigger the protective response of heat shock proteins. The specification is replete with references to the cardioprotective effect of HSPs as it relates to Motamedi's invention. *See, e.g.,* col 5, lines 12-18 and lines 34-38; *see also* col. 7, lines 22-30; col. 4, lines 21-26, etc. The fact that HSPs are central to the invention of Motamedi is evident from Motamedi's own assertion that his invention fills the need "for a method of directly heating the heart and inducing regional HSP expression, thus avoiding the limitations that may be induced during whole body hyperthermia." *See* col. 2, lines 32-36.

In contrast to Motamedi, Chen '478 teaches flexible substrates having various electrical circuits mounted thereon. In one variation, the flexible substrate has light emitting sources mounted thereon for use in PDT. However, the PDT taught by Chen '478 is used to destroy

abnormal cells, useful in the treatment of certain malignant tumors. *See* col. 1, lines 25-33. This is because, as Chen '478 notes, abnormal cells absorb more photoreactive dye than normal cells, and are, therefore, destroyed in greater proportion than normal cells upon radiation with light. *Id.* Noticeably, Chen '478 fails to teach the use of PDT for treating atrial arrhythmias, or even suggest why the use of PDT for treating atrial arrythemias may be desirable. In fact, the only mention in Chen '478 of the heart is regarding one of Chen's devices used in the treatment of arteriosclerotic deposits inside arteries. *See* col. 15, line 55 through col. 16, line 16.

In contrast to both Motamedi and Chen '478, Lesh teaches methods of forming circumferential conduction blocks in the heart tissue of patients diagnosed with an atrial arrhythmia. The block isolates electrical conduction between opposite longitudinal portions of the pulmonary wall relative to the conduction block and along the longitudinal axis, preventing an atrial arrythmia. *See* col. 9, lines 64-67. Lesh teaches nothing of PDT for treating atrial arrythmias, and similarly fails to suggest why using PDT may be desirable.

One having ordinary skill in the art would not look to combine the conductive isolation methods of Lesh, with the HSP response methods of Motamedi, with the light therapy methods of Chen. As noted above, the methods themselves, and the mechanisms by which they produce their effect, are very different. An attempt to combine these references would change the principle of operation each reference relies upon to produce its therapeutic effect. Thus, no reasonable expectation of success may be assumed upon combination of these references. The Office Action fails to provide any evidence to the contrary.

Therefore the rejections under 35 U.S.C. §103(a) are improper and should be withdrawn.

Claim 24

Claim 24 stands rejected under 35 U.S.C. §103(a) over Chen '478 in view of U.S. Patent No. 5,957,960 to Chen *et al.* (Chen '960). In support of this rejection the Office Action states that "Chen '960 teaches lenses within the LED light sources (Fig. 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the

lenses as taught by Chen '960 in the invention of Chen '478 to achieve the desired light pattern." Claim 22, from which claim 24 depends, has been amended. Claim 22 was discussed in detail above.

Applicant submits that in view of the above amendment, the rejection of claim 24 under 35 U.S.C. §103(a) is moot. Withdrawal of this rejection is requested.

CONCLUSION

Applicant has responded to each matter of substance raised in the Office Action and submits that the case is in condition for allowance. Should the Examiner have any requests, questions, or suggestions, he is invited to contact Applicant's attorney at the number listed below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 473912000100.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

1. (Twice Amended) A method for producing patterned lesions [having predetermined lesion patterns] in cardiac tissue comprising the step of subjecting [a] cardiac tissue containing a photodynamic drug to a light source [arranged in a predetermined pattern to form a lesion corresponding to that predetermined pattern], the light source arranged so as to produce a lesion in a pattern corresponding to the light source.

11. (Twice Amended) A method for the heat-free treatment of a selected cardiac tissue comprising the step of subjecting said cardiac tissue containing a photodynamic drug to a light source [to form a lesion in a predetermined pattern on said cardiac tissue], the light source arranged so as to produce a lesion in a pattern corresponding to the light source.

22. (Twice Amended) A light delivery device for providing light to a cardiac tissue comprising a generally linear member having a distal region, [with] said distal region comprising an axis, [said distal region having a substantially clear and linear] and a transparent linear light emitting region corresponding to [said] the axis, [said light emitting region being conformable to a curved cardiac tissue and emitting substantially all the light emanating from the device] the linear light emitting region being surrounded by a substantially opaque region and emitting substantially all light emanating from the device to produce a lesion in a pattern corresponding to the light emitting region, the linear light emitting region further being conformable to a curved cardiac tissue.